95-1336 No.

Supreme Court, U.S.
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In The

Supreme Court of the United States

October Term, 1995

ADA M. MARTIN and HAROLD L. MARTIN,

Petitioners,

vs.

TELECTRONICS PACING SYSTEMS, INC.; TPLC INC., doing business as Telectronics Pacing Systems; Telectronics PTY Limited,

Respondents.

Petition for Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Do the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360c, *et seq.*, preempt state law tort claims to recover for injuries caused by a defective medical device?

2. Does preemption of state law tort causes of action under the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act violate Petitioners' right to a jury trial under the Seventh Amendment to the United States Constitution?

RULE 29.6 STATEMENT

To the best of the knowledge of counsel for the Petitioners, all parties including all divisions of the corporate Respondents are contained in the caption of the case.

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Petitioners Ada M. Martin and Harold L. Martin, hereby petition for review of a ruling of the United States Court of Appeals for the Sixth Circuit entered in the above-entitled proceeding on November 20, 1995.

The Sixth Circuit held that Petitioners' state law product liability claims against respondent for injuries allegedly received from use of its ATP 4210 Implantable Cardioveter/ Defibrillator-Demand Pacemaker were expressly preempted by 21 U.S.C. § 360k(a) of the Medical Device Amendment to the Federal Food, Drug and Cosmetic Act. The federal preemption issues raised in this case are very similar to those raised in the petition in *Medtronic, Inc. v. Lohr*, No. 95-754, and in the cross-petition, *Lohr v. Medtronic, Inc.*, No. 95-886, the Writs in both cases being granted by this Court on January 19, 1996. The reasons for granting the petition in this case as to those issues are accordingly argued in similar terms.

The Sixth Circuit also held that Petitioners' claim that the Seventh Amendment to the United States Constitution precludes Congress from preempting a state tort remedy under the facts and circumstances of this case was without merit. This is a constitutional issue never considered by this Court and is one that deserves this Court's opinion particularly in relationship to the issue of federal preemption as raised in this case and in the two previously cited cases in which this Court has already granted the Writs of Certiorari.

Because the MDA preemption issues were explicitly briefed in the two previously-cited petitions, Petitioners will address their constitutional issue first, and the preemption issue second. To the extent possible, Petitioners will attempt to avoid repeating the background information already contained in the *Medtronic* and *Lohr* petitions.

While Petitioners believe that this Court will not reach the constitutional issues but can and will reach a favorable decision with the appropriate interpretation limiting the scope of the preemption language contained in the MDA. However, if this Court chooses to adopt the holding of the Circuit Court as to the issue of preemption, then the Petitioners would submit that such interpretation makes the preemption provision of the Act unconstitutional. They are not unmindful that a basic tenet of statutory construction is that a court is required if at all possible to construe a statute in such a manner as to uphold its constitutionality. *United States v. Thirty Seven Photos*, 28 L. Ed. 2d 822 (1971). They believe that this case can be resolved in their favor without the necessity of declaring an Act of Congress unconstitutional.

OPINIONS BELOW

The opinion of the Court of Appeals is reported at 70 F. 3d 39 (6th Cir. 1995) and is reproduced in the appendix to the petition. Pet. App. A at p. 1a. The opinion and order of the United States District Court for the Southern District of Ohio, Eastern Division, granting on December 14, 1993, partial summary judgment to the Respondents is unreported and is reproduced in the appendix to the petition. Pet. App. C at p. 17a. The memorandum and order and judgment of the United States District Court for the Southern District of Ohio, Eastern Division,. granting summaryjudgment on September 7, 1994, to the Respondents is unreported and is reproduced in the appendix to the petition. Pet. App. B at p. 8a.

STATEMENT OF JURISDICTION

The Court of Appeals entered judgment on November 20, 1995. This Court has jurisdiction under 28 U.S.C. § 1254(1).

Rule 29.4(b) Statement

The constitutionality of an Act of Congress is drawn into question. Accordingly, 28 U.S.C. § 2403(a) may apply. The United States Court of Appeals for the Sixth Circuit and the United States District Court for the Southern District of Ohio, Eastern Division, did not certify to the Attorney General pursuant to 28 U.S.C. § 2403(a) the fact that the constitutionality of an Act of Congress was drawn into question. Three copies of this petition were served by Lutz Appellate Services, Inc. on the Solicitor General of the United States at Room 5614, Department of Justice, 10th Street and Constitution Avenue, N.W., Washington, D.C. 20530, at the time of its filing with the Clerk of this Court.

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED

The principal constitutional provisions, statutes and regulations involved in this case are reproduced in the appendix to this petition. Pet. App. D at pp. 29a-55a.

STATEMENT OF THE CASE

A. Facts and Lower Court Proceedings.

On March 31, 1992, doctors surgically implanted in Petitioner, Ada Martin, a Guardian 4210 Cardioveter/ Defibrillator System manufactured and/or supplied by Respondents. This system was composed of four component parts: Model 4210 defibrillator, Model 040-106 leads, Model 033-572 leads, and Model 033-415 Y-adaptor. A defibrillator functions by detecting abnormal heart rhythms and by generating an electrical shock to the heart muscle. The shock acts to terminate the detected arrhythmia and to restore a rhythm of heart contractions which conforms to that programmed within

the defibrillator. The device at issue functions with a design which provides combined functions of a defibrillator with a cardioveter and a pacemaker.

The Guardian 4210 System, including all four component parts, is a medical device currently subject to investigational testing pursuant to the Medical Device Amendments to the 1938 Food, Drug and Cosmetic Act ("MDA") and pursuant to regulations promulgated under MDA by the United States Food and Drug Administration ("FDA"). At all times relevant to this case, the product system had secured "investigational device exemption" ("IDE") under MDA.

Mrs. Martin's implanted Guardian 4210 System began to malfunction subsequent to March 31, 1992, which required surgical replacement of the system on November 19, 1992. As a result of the malfunction, Mrs. Martin claims that she suffered trauma to her body structure, permanent physical pain, anxiety, mental distress, loss of enjoyment of life, inability to perform ordinary activities, and physical impairment. She also claims that she will incur medical expenses in the future and lost income in the future. Her husband claims derivatively that he has lost services, companionship, and consortium now and in the future. They claim damages in the amount of $500,000, together with interest and costs.

Petitioners, Ada and Harold Martin, initiated this action on May 14, 1993, in the Common Pleas Court of Franklin County, Ohio. The Respondents, Teletronics, Inc., et al., filed their Notice of Removal on June 10, 1993, and the Petitioners thereafter filed a Motion to Remand which was overruled by the District Court. Both parties moved for partial summary judgment, and by way of Opinion and Order filed on December 14, 1993, (Pet. App. C at pp. 17a-28a), the District Court granted Respondents' Motion and overruled the Petitioners' Motion. On

February 23, 1994, the District Court issued an Order permitting the Petitioners to file an Amended Complaint. The Amended Complaint asserted the same claims for relief as the original Complaint, but also added claims relating to additional components of the Guardian 4210 System. Thereafter, the parties filed Cross-Motions for Summary Judgment. Respondents asserted that the Petitioners' Ohio statutory and common law claims for damages based upon product liability and loss of consortium were pre-empted by 21 U.S.C. § 360k(a). The Petitioners asserted that their state law claims were not preempted because of the language contained in 21 U.S.C. § 360h(d) and 21 C.F.R. § 808.1(d), and also, that if their claims were not pre-empted, such pre-emption by Congress would violate the Seventh Amendment to the United States Constitution. The District Court issued its Decision and Judgment on September 7, 1994, (Pet. App. B" at p. 8a), granting Respondents' April 29, 1994, Motion for Summary Judgment, dismissing the Complaint of the Petitioners and entering Judgment in favor of Respondents. The District Court's Decision was based upon a finding of federal preemption of state tort law. The court did not address the issue of whether or not failure of Congress to provide for a tort remedy violates the Seventh Amendment to the United States Constitution. The Petitioners filed their Notice of Appeal in the District Court on September 20, 1994, and the Petitioners timely filed their brief in the Sixth Circuit United States Court of Appeals on November 7, 1994. That court issued its decision affirming the District Court on November 20, 1995.

B. Jurisdiction in the Lower Courts.

The jurisdiction of the United States District Court for the Southern District of Ohio, Eastern Division, was based upon diversity jurisdiction as set forth in Title 28, Section 1332, United States Code. The Petitioners are residents of the Southern

District of Ohio. The Respondents are business entities having their principal place of business in the State of Colorado, and the amount in controversy exceeded $50,000. The District Court also had federal question jurisdiction under Title 28, Section 1331, United States Code, because of the issue of federal preemption. The jurisdiction of the United States Court of Appeals for the Sixth Circuit was based upon Title 28, Section 1291, United States Code.

C. The Decision of the Court of Appeals.

The Sixth Circuit expressly held that 21 U.S.C. § 360k(a) preempted the Petitioners' state law products liability claims. It recited that it joined the majority of circuits which had considered the issue: *Mitchell v. Collagen Corp.*, No. 94-3946, 1995 WL 576949 (7th Cir. Oct. 2, 1995); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995); *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995); *Martello v. CIBA Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993).

Importantly, the court acknowledged that the Ninth Circuit in *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995) specifically held otherwise, and that there was disagreement among several of the Circuits on whether or not state express warranty claims were preempted.

The Sixth Circuit then turned to Petitioners' "unique Seventh Amendment Claim", and held that it was without merit, citing the Ninth Circuit's decision in *Spinelli v. Gauglin*, 12 F.3d 853, 858 (9th Cir. 1993) as authority for its decision.

REASONS FOR GRANTING THE WRIT

I.

THIS CASE PRESENTS A CONSTITUTIONAL ISSUE OF FIRST IMPRESSION THAT SHOULD BE DECIDED BY THIS COURT.

What was the purpose of adding the Seventh Amendment to the United States Constitution in 1791? Does the Seventh Amendment place restrictions on Congress' powers to enact certain laws? These two questions have never been answered by this court in any context, and most particularly, this court has never addressed the question of whether or not the doctrine of federal preemption is limited by the provisions of the Seventh Amendment.

During the past sixty years, Congress through legislation adopted pursuant to the commerce clause contained in Article I, Section 8 of the United States Constitution has involved the federal government in virtually every aspect of the ordinary citizen's life - from birth to death. The federal courts in most cases have permitted Congress and the federal bureaucracy to prevail under the auspices of the Supremacy Clause contained in Article VI. It seems that Congress and the courts have forgotten that the federal government was purposely created to be one of limited powers. Two of the first ten amendments make the doctrine of a limited federal government abundantly clear:

AMENDMENT IX

> The enumeration in he Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.

AMENDMENT X

> The powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people.

The purpose of the adoption of the Bill of Rights in 1791 was to correct what the citizens perceived as too much power being given to the federal government in the Constitution as ratified in 1787.

Each of the first ten amendments further restricted the power of the federal government to intrude in the affairs of the states and of this country's individual citizens. The Seventh Amendment provides:

> In suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any court of the United States, than according to the rules at common law.

Petitioners submit that this amendment places limitations on Congress that have never been considered by this court.

The Sixth Circuit in its opinion acknowledged that the petitioners raised a "unique Seventh Amendment claim". It ignored the petitioners' claim stating at 70 F. 3d 39, 42 (6th Cir. 1995):

> Nothing in its text or history indicates that the Seventh Amendment protects the existence of certain common-law causes of action. The

> Seventh Amendment protects a litigant's right to a jury trial where there exists a cause of action at common law, or one analogous thereto, for legal relief, where the amount in controversy exceeds twenty dollars. *Tull v. United States*, 481 U.S. 412, 417-18 (1987). Here, as plaintiffs' causes of action have been preempted by federal law, they have no "suit[] at common law" and the Seventh Amendment's guarantees are not implicated. We agree with the Ninth Circuit, which addressed this issue in the context of ERISA's preemption of state common-law causes of action:
>
> Congress surely can preempt a state cause of action, be it legal or equitable: This is the very nature of federal supremacy. Once Congress has chosen to preempt the state claim, it's free to give affected individuals a full federal claim, a claim providing only for remedies limited to equity, a damages claim only, or no claim at all. The Seventh Amendment, again, does not stand in the way.
>
> *Spinelli v. Gaughn*, 12 F.3d 853, 858 (9th Cir. 1993) (footnote omitted)
>
> Accordingly, plaintiffs' Seventh Amendment claim must fail.

It is important to note that neither the Sixth Circuit nor the Ninth Circuit cited any decisions of this court where this court held that federal preemption is not limited by the Seventh Amendment. Those federal courts, like countless others,

assumed that the Supremacy Clause has no limits. History indicates otherwise.

Congress adopted the 1938 Food, Drug, and Cosmetic Act and the 1976 Medical Device Amendments thereto pursuant to the power granted to it in the Commerce Clause contained in Article I, Section 8 of the United States Constitution. The doctrine of preemption arises from the Supremacy Clause contained in Article VI of the Constitution. Both of these provisions were in the Constitution as it was ratified in 1787.

As the Constitution was being drafted during the summer of 1787, one of the issues which stirred great debate was whether the Constitution ought to contain certain guarantees to the people, including the right to a jury trial in civil cases. Ultimately, such a provision was omitted but the omission almost caused the Constitution not to be ratified by the states. It was only the promise that the right to a jury trial in civil cases would be included in the proposed Bill of Rights that carried the day for ratification. The Antifederalists made three principle arguments in favor of the inclusion of the right to trial by jury in civil cases: the protection of debtors, the frustration of unwise legislative and administrative policies of the federal government, and the control of corrupt judges. The right to a jury trial in a civil case was embodied in the Seventh Amendment which was ratified on December 15, 1791. (The foregoing history was abstracted from Wolfram, *The Constitutional History of the Seventh Amendment* 57 Minnesota L. Rev. pp. 639-747 (1973)). (Pages 705-708 are reproduced in the appendix, (Pet. App. E at pp. 56a-60a), because they contain a review of the historical materials available concerning this aspect of the Seventh Amendment during the ratification debates prior to the adoption of the Bill of Rights in 1791.) Contrary to the assertion of the Sixth Circuit, history does support the argument that one of the purposes of the Seventh Amendment was to limit the power of Congress to pass certain laws.

This Court has historically and consistently used the historical approach in its interpretation of the Seventh Amendment. *Compare* Mr. Justice Story's opinion in *United States v. Wonson*, 28 F. Cas. 745, 750 (No. 16,750) (C.C.D. Mass. 1812) *with* Mr. Justice White's opinion writing for a unanimous court in *Wooddell v. Electrical Workers*, 502 U.S. __, __; 116 L. Ed. 2d 419, 427 (1991), and the cases cited therein. Our modern tort law traces its history in England to the action of trespass which first appeared in the thirteenth century and then developed into trespass on the case which existed in England long before 1791. *See* Prosser, *Handbook of the Law of Torts*, 4th ed. West Publishing Co., 1971, p. 28. This Court has always begun its Seventh Amendment decisions by considering the common law as it existed in the 18th century, but this Court's cases have only considered whether a litigant was entitled to a jury trial in the circumstance where a cause of action was already acknowledged to exist. *See, e.g., Wooddell v. Electrical Workers, op. cit.*, (did petitioner have a right to have his LMRDA claim tried to a jury); *Tull v. United States*, 481 U.S. 412 (1987), (did petitioner have a right to trial by jury on his liability and amount of penalty under the Clean Water Act); and *Local No. 391 v. Terry*, 494, U.S. 558 (1990), (did petitioner have a right to have his action for breach of a union's duty of fair representation determined by a jury). None of the foregoing cases nor any other case of this Court ever determined whether or not the Seventh Amendment preserved a cause of action in and of itself.

While there is no doubt that Congress has broad power to legislate in subject areas specified in the Constitution, that power is not without limit. As the Supreme Court has said, "The touchstone of due process is the protection of the individual against arbitrary actions of the government." *Daniels v. Williams*, 474 U.S. 327, 88 L. Ed. 2d 662, 668 (1986) quoting *Dent v. W. Va.*, 32 L. Ed. 623 (1989). If Congress has provided no tort remedy for injury caused by a medical device and at the same

time has preempted a state law tort claim, it has acted both arbitrarily and in contravention of the Seventh Amendment because tort claims trace their history in England to a date prior to 1791 and Congress, therefore, has no authority to prohibit the cause of action from being determined by a jury.

There is no doubt that Petitioner's Seventh Amendment claim is novel. At some point in our history all constitutional issues were novel when first raised by a party. A relatively recent example is the concept of constitutionally protected personal privacy. The term "privacy" is nowhere to be found in the United States Constitution and was not recognized as a protected right until Justice Douglas' opinion in *Griswold v. Connecticut*, 381 U.S. 479 (1965). Obviously, today it is not a novel theory, nor is there a paucity of case law espousing its importance as a concept of constitutional law.

Petitioners' position is simple and straightforward: The Seventh Amendment limits the authority of Congress to enact certain laws; Congress cannot pass a law that abrogates an individual's right to a trial by jury where the cause of action existed prior to 1791; and the Seventh Amendment as an amendment takes precedence over the Supremacy Clause. This issue is of great national importance, and accordingly, Petitioners request this court to grant their petition and finally address this issue.

II.

THE DECISION BELOW CONFLICTS WITH DECISIONS OF OTHER COURTS OF APPEAL AND INTERPRETS THE STATUTE, 28 U.S.C. § 360k(a), CONTRARY TO CONGRESSIONAL INTENT.

The Sixth Circuit Court of Appeals held that all of

Petitioners' state tort claims were preempted by 21 U.S.C. § 360k(a). The Medical Device Amendment to the Food, Drug and Cosmetic Act, stating simply that the Sixth Circuit chose to join the majority of other Circuits which had decided the issue which includes decisions previously cited herein from the First, Third, Fourth, Fifth, Seventh, Eighth, and Eleventh Circuit Courts of Appeals. The Sixth Circuit also acknowledged that the Ninth Circuit in *Kennedy v. Collagen Corporation*, 67 F.3d 1453 (9th Cir. 1995) had specifically held that state tort law claims were not preempted by the MDA.

Effective January 5, 1988, the Ohio General Assembly enacted statutes which addressed the standards for establishing both liability and defenses for products liability damage claims for personal injury, wrongful death, and property damage. Sections 2307.71, *et. seq.*, Ohio Revised Code. Copies of the relevant sections are contained in the Pet. App. D at 31a-52a.

Under Section 3(B) of Amended Substitute House Bill 1 ("H.B.1"), and pursuant to R.C. Section 2307.72, with limited exceptions, the Ohio General Assembly declared that the new statutory framework exclusively controls product liability damage claims which arise in Ohio. Announcing prospective application, Section 3(B) of H.B. 1 reads as follows:

> The provisions of Sections 2307.71, 2307.72, 2307.73, 2307.74, 2307.75, 2307.76, 2307.77, 2307.78, 2307.79, 2307.80, and 2315.20 of the Revised Code as enacted by this Act and the repeal of section 2305.33 of the Revised Code by this Act shall apply only to product liability actions that are commenced on or after the effective date of this act and that are based upon claims for relief that arise on or after that date.

R.C. Section 2307.72 declares that Ohio's new statutory framework substantially replaced Ohio's common law of product liability. In pertinent part, R. C. Section 2307.72 reads as follows:

> (A) Any recovery of compensatory damages based on a product liability claim is subject to sections 2307.71 to 2307.79 of the Revised Code.
>
> (B) Any recovery of punitive or exemplary damages in connection with a product liability claim is subject to sections 2307.71 to 2307.80 of the Revised Code.

The First Cause of Action of Petitioners' Complaint alleged manufacturing defect under R. C. Section 2307.74. The Second Cause of Action contended that Respondents' product is defectively designed under the standards of R.C. Section 2307.75. The Third Cause of Action pleads that Respondents inadequately warned or instructed contrary to R. C. Section 2307.76 with respect to the products. The Fourth Cause of Action, alleged that Petitioners violated R. C. Section 2307.77 by nonconformance to express representation of material facts concerning the products. The Fifth Cause of Action contended that Respondent is subject to liability as a supplier of the products under R. C. Section 2307.78. Mr. Martin pleads a derivative spousal claim in the Sixth Cause of Action of the Complaint.

The subject claims are clearly claims of strict products liability imposed by the state statutory law and not negligence claims as alleged by Respondents. The Petitioners would emphasize to this Court that after January 5, 1988, *all* products liability actions are controlled by Section 2307.71, *et seq.* of the Ohio Revised Code.

Yet, the Ohio General Assembly enacted no statutory language in H.B. 1 in which acknowledged and accepted federal preemption by MDA or by any other federal law which somehow arguably relates to Ohio's statutory product liability claims. The importance of the Ohio General Assembly's omission to mention MDA is underscored by the Ohio General Assembly's specific acknowledgement that approval of drugs issued by the "Federal Food and Drug Admimostration under the Federal Food, Drug and Cosmetic Act ("FDCA"), 52 Stat. 1040, 21 U.S.C. §§ 301-392 as amended" defeats any punitive damage claim against a manufacturer or supplier of the drug. Section 2307.80, Ohio Revised Code. Obviously, the Ohio legislature was well aware of the federal statutes which are at issue in this case; yet, the General Assembly specifically acknowledged FDCA and applied FDCA only in a limited capacity as to Ohio's products liability statutes.

When this Court reviews the difference of opinion among the Circuits, as to the application of the MDA, it will notice that the Circuits which found preemption to apply uniformly held that the following language of 21 U.S.C. § 360k(a) required that finding:

State and local requirements respecting devices

(a) General rule

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

An example of those Circuits' reasoning is set forth in *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392, 397 (4th Cir. 1995):

> The language of this section expressly reveals congressional intent that the MDA preempt state-imposed requirements that are different from or additional to those applicable to the device under Chapter 9 of Title 21 and that relate either to the safety or effectiveness of the device or to other matters encompassed in requirements applicable to the device under Chapter 9 of Title 21. The question then becomes whether state-law claims may impose requirements within the meaning of § 360k. We conclude that they may.

Those Circuits usually cite this Court's decision in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) as justification for their conclusion. However, Petitioners submit that this line of reasoning is incorrect because it is incomplete.

Congress also provided in the MDA at 21 U.S.C. § 360h(d) that:

> Compliance with an order [requiring a manufacturer to repair, replace, or provide reimbursement for expenses relating to an unsafe device] issued under this section shall

> not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

As Judge Spiegel said in *Mulligan v. Pfizer, Inc.*,850 F. Supp. 633, 636 (S.D. Ohio 1994):

> Thus, this paragraph [21 U.S.C. § 360h(d)] specifically contemplates state law liability and damages.

Courts cannot ignore language contained within an Act of Congress. As the Fifth Circuit Court of Appeals observed in 1954:

> It is, of course, elementary that a statute should be so construed as to give it a field of operation as to make it an effective law. The legislature is never presumed to have done a vain thing in the enactment of a statute.

Imperial Production Corp. v. City of Sweetwater, 210 F.2d 917, 920 (5th Cir. 1954). Additionally, the FDA has recognized that state tort law has not been totally preempted as provided in its interpretation of § 360k found at 21 C.F.R. § 808.1(d) (1) (App. D at p. 54a) where it said, "Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates . . . to products in addition to devices . . .", and most particularly the advisory opinion of FDA's Office of Chief Counsel,

> Under section 521(a) [21 U.S.C. § 360k] of the act, the act preempts only state and local requirements that directly and specifically relate to devices. For a State provision to be a requirement with respect to a device within the meaning of section 521 of the act, and thereby a candidate for preemption relate to the device itself. There is no indication in the legislative history of section 521(a) that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies, or State or local statutes that only incidentally apply to devices. Rules or requirements established by States to govern the legal remedies available under the State judicial system are not "requirements with respect to a device" within the meaning of Section 521(a) of the act.

As cited in *Ministry of Health v. Shiley*, 858 F. Supp. 1426, 1435 (C.D. Cal. 1994).

An agency's interpretation of its own statute is controlling so long as that interpretation is not contrary to the intent of Congress. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984).

The Ninth Circuit well-stated the proper conclusion in *Kennedy v. Collagen Corp., supra*, at 1459-1460, when it held,

> The federal law requiring the premarket approval of Class III devices as not enacted in order to free manufacturers from the everyday burdens of the marketplace after

> they are permitted to enter it. Premarket approval is supposed to benefit consumers, not create a rose garden, free from liability, for manufacturers. Courts which have held to the contrary have done so in contravention of the FDA's regulations and statements concerning the preemptive scope of the MDA. The FDA's determination that § 360k(a) must be read narrowly establishes a plausible interpretation of the statute and comports with the congressional intent behind the legislation. Absent a compelling reason to overturn the FDA's interpretation of the legislation, we must adopt that interpretation and reverse the district court's grant of summary judgment.

The foregoing analysis does not ignore the following pronouncements of this Court:

> (1) In making an analysis as to whether there is federal preemption of state law, there is a "strong presumption against preemption", which may only be overcome by a clear and manifest intention of Congress to take away tort rights existing under state law.

Cippollone, supra, at 422, citing *Rice, supra*, at 230. *See also, Hillsboro County, Florida v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 713 (1985).

> (2) This presumption against federal legislative preemption of states law becomes even more compelling where the purported preemption would usurp the power of the

> state to protect the health and safety of its citizens.

Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947).

> (3) Where a finding of federal preemption of common law tort claims would leave the injured person without any state or federal remedy, the court has authority to find preemptive intent only under extreme conditions.

Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984).

Accordingly, this Court should grant the Petition in order to standardize the law as it is interpreted and applied in all federal jurisdictions.

CONCLUSION

For all the reasons stated, Petitioners, Ada M. Martin and Harold L. Martin pray that this Court grant a Writ of Certiorari to review the decision of the United States Court of Appeals for the Sixth Circuit.

Respectfully submitted,

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APPENDIX A — DECISION OF THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT FILED NOVEMBER 20, 1995

No. 94-4003

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

ADA M. MARTIN; HAROLD L. MARTIN,

Plaintiffs-Appellants,

v.

TELECTRONICS PACING SYSTEMS, INC., et al.,

Defendants-Appellees.

ON APPEAL from the United States District Court for the Southern District of Ohio

Decided and Filed November 20, 1995

Before: KENNEDY and MOORE, Circuit Judges; JOHNSTONE, District Judge.*

KENNEDY, Circuit Judge. Plaintiffs, Ada and Harold Martin, appeal from a grant of summary judgment for defendants in this diversity action alleging state product liability and related tort claims arising out of the implantation of an experimental medical device. The District Court held that federal law

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* The Honorable Edward H. Johnstone, United States District Judge for the Western District of Kentucky, sitting by designation.

preempted plaintiffs' claims. Plaintiffs appeal this decision and also argue in the alternative that if their claims are preempted, it is a violation of their Seventh Amendment right to a jury trial. We disagree, and for the following reasons AFFIRM the decision of the District Court.

I.

Medical devices intended for human use are heavily regulated by the Food and Drug Administration pursuant to the Medical Device Amendments to the Food, Drug and Cosmetics Act ("MDA"), 21 U.S.C. § 360c. In order "to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use," the MDA exempts certain "investigational devices" from FDA performance standards and premarket approval. 21 U.S.C. § 360j(g).[1] Investigational devices are instead subject to a different set of complex and comprehensive regulations. *See, e.g.*, 21 U.S.C. § 360j(g)(3); 21 C.F.R. §§ 812.20, 812.25, 812.27.

The Telectronics Guardian ATP 4210 Implantable Cardioverter-Defibrillator-Demand Pacemaker ("device") is an investigational medical device not yet approved by the FDA for general release to the marketplace. It combines the functions of a defibrillator, a cardioverter, and a pacemaker. The device is implanted into the patient's body and generates electrical shocks, when necessary, to maintain a normal heart rhythm.

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1. Were it not for its investigational status, the product at issue would have been regulated as a Class III medical device. *See* 21 C.F.R. §§ 870.3610, 870.3680, 870.5300.

Appendix A

On the morning of March 31, 1992, plaintiff Ada Martin signed a form consenting to implantation of the device to correct a heart ailment. Later that day, doctors at the Ohio State University Hospitals implanted the device into Ada Martin's chest. Plaintiffs claim that the device began to malfunction sometime after the operation and was therefore replaced in a subsequent operation on November 19, 1992. As a result of the alleged malfunction of the device, plaintiffs claim that they have suffered $500,000 in damages.

Plaintiffs allege five causes of action under Ohio products liability law, Ohio Rev. Code §§ 2307.74-.78. Specifically, the complaint alleges that the defendant (1) defectively manufactured the device; (2) defectively designed the device; (3) failed to adequately warn plaintiffs; (4) failed to conform to certain unidentified "express representations"; and (5) supplied the device in question to plaintiffs. Ada Martin's spouse also pleaded a derivative common-law tort claim alleging that he suffered loss of consortium and companionship as a result of defendant's conduct.

Defendant filed for summary judgment on these claims arguing that they were preempted by MDA § 360k(a).[2] In

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2. This section states, in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(Cont'd)

response, plaintiffs sought a declaration that their state claims were not preempted. In a series of two opinions and orders, the District Court granted defendant's motion, holding that § 360k(a) preempted plaintiffs' claims. Plaintiffs now appeal, arguing that the District Court erred in holding that their claims were preempted and, alternatively, that if their claims are preempted, the MDA violates their Seventh Amendment right to a jury trial.[3]

II.

The issue raised by plaintiffs' first argument is whether MDA § 360k(a) preempts their state law products liability and derivative state common-law claims. Several courts of appeals have previously addressed this question and have held similar state law claims preempted. *See Mitchell v. Collagen Corp.*, No. 94-3946, 195 WL 576949 (7th Cir. Oct. 2, 1995); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995); *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995); *Martello v. CIBA Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d

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(Cont'd)

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

3. Appellants also raise a Fifth Amendment substantive due process argument. However, this argument was not raised before the District Court and it has therefore been waived. *Bricker v. Voinovich*, 977 F.2d 235, 238 (6th Cir. 1992), *cert. denied*, 113 S. Ct. 2965 (1993).

Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993). *But see Kennedy v. Collagen Corp.*, No. 94-15197, 1995 WL 606511 (9th Cir. Oct. 17, 1995) (holding state law claims not preempted where FDA had established no specific requirements unique to the Class III medical device at issue). We now join the majority of circuits and hold that § 360k(a) of the MDA expressly preempts plaintiffs' state law product liability claims.

There is disagreement as to whether this section also preempts claims for breach of an express warranty. *Compare King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir.) (holding express warranty claims preempted), *cert. denied*, 114 S. Ct. 84 (1993) *and Duvall*, 65 F.3d at 400-01 (holding express warranty claims based on FDA-mandated labeling, packaging, or advertising preempted) *with Michael v. Shiley, Inc.*, 46 F.3d 1316, 1327 (3rd Cir.) (holding express warranty claims not preempted), *cert. denied*, 116 S. Ct. 67 (1995) *and Mitchell*, __ F.3d at __ (following *Michael*). We conclude that, in the context of investigational devices, express warranty claims are also preempted.

Express representations made about investigational devices are subject to comprehensive FDA regulation. For example, 21 C.F.R. § 812.5 mandates the contents of investigational device labels; § 812.7 prevents the commercialization and promotion of investigational devices, and prohibits any representation that "an investigational device is safe or effective for the purposes for which it is being investigated"; and § 812.25(f) requires submission of all investigational device labeling to the FDA for approval. Thus, the representations that can, cannot, and must be made about an investigational device are all determined by the FDA.

Plaintiffs' advance an express warranty claim under state law of "nonconformance to express representations concerning the character, quality, and/or safety of the device." Because such a claim would, in effect, impose a requirement "different from or in addition to" an FDA regulation "which relates to the safety or effectiveness of the device," we hold that it is preempted by § 360k(a). *See Duvall*, 65 F.3d at 40-01; *King*, 983 F.2d at 1135. *See also Talbott*, 63 F.3d at 31 (reaffirming *King*).

We now turn to plaintiff's unique Seventh Amendment claim.

III.

The Seventh Amendment states, in relevant part: "In suits at common law, where the value in controversy shall exceed twenty dollars, the right of a trial by jury shall be preserved . . . ." U.S. Const. amend. VII. Plaintiffs interpret this to mean that the federal government cannot preempt a state tort remedy if it provides no analogous tort remedy at federal law "because tort claims trace their history in England to a date prior to 1791 and Congress, therefore, has no authority to prohibit the cause from being considered by a jury."

We disagree. Nothing in its text or history indicates that the Seventh Amendment protects the existence of certain common-law causes of action. The Seventh Amendment protects a litigant's right to a jury trial where there exists a cause of action at common law, or one analogous thereto, for legal relief, where the amount in controversy exceeds twenty dollars. *Tull v. United States*, 481 U.S. 412, 417-18 (1987). Here, as plaintiffs' causes of action have been preempted by federal law, they have no "suit[] at common law" and the Seventh Amendment's

guarantees are not implicated. We agree with the Ninth Circuit, which addressed this issue in the context of ERISA's preemption of state common-law causes of action:

> Congress surely can preempt a state cause of action, be it legal or equitable: This is the very nature of federal supremacy. Once Congress has chosen to preempt the state claim, it's free to give affected individuals a full federal claim, a claim providing only for remedies limited to equity, a damages claim only, or no claim at all. The Seventh Amendment, again, does not stand in the way.

Spinelli v. Gaughn, 12 F.3d 853, 858 (9th Cir. 1993) (footnote omitted). Accordingly, plaintiffs' Seventh Amendment claim must fail.

IV.

For the foregoing reasons, the judgment of the District Court is hereby AFFIRMED.

APPENDIX B — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO, EASTERN DIVISION FILED SEPTEMBER 7, 1994

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

Case No. C2-93-580

Ada M. Martin, et al.,

Plaintiffs,

vs.

Telectronics Pacing Systems, Inc., et al.,

Defendants.

MEMORANDUM AND ORDER

Plaintiffs Ada and Harold Martin initiated this action on May 14, 1993, asserting numerous state law causes of action arising from Ada Martin's use of an implanted medical device known as the Guardian 4210 Cardioverter/Defibrillator System (the "Guardian 4210 System"). The defendants allegedly designed, manufactured, and supplied the Guardian 4210 System. The Guardian 4210 System consists of at least four parts: (1) a cardioverter/defibrillator (the "Defibrillator"); (2) model 040106 connectors (the "Connectors"); (3) model 033-572 sense/pace leads (the "Leads"); and (4) a model 033-415 adapter (the "Adapter"). This matter is now before the Court on Defendants' April 29, 1994 motion for summary judgment.

Appendix B

On March 31, 1992, doctors implanted the Guardian 4210 System in plaintiff Ada Martin. The parties agree that, at the time the system was implanted in Mrs. Martin, it was not approved by the Federal Food and Drug Administration (the "FDA") and was undergoing investigative study. The parties further agree that Ada Martin had consented to participate in the study of the Guardian 4210 System. On November 19, 1992, Ada Martin underwent a second surgical procedure during which physicians removed the Guardian 4210 System and replaced it with an alternate system. Pursuant to their initial complaint, plaintiffs alleged that the Connectors, the Leads, and the Defibrillator were defectively designed and manufactured and that Ada Martin was injured as a result of the defects and the resulting necessity of a second invasive surgical procedure. Mrs. Martin asserted five causes of action arising under Section 2307 of the Ohio Revised Code ("O.R.C."). Specifically, she asserted claims under O.R.C. §§ 2307.74, .75, .76, .77, and .78 related to the Defibrillator, the Connectors, and the Leads. Mr. Martin asserted a cause of action based upon Ohio common law for loss of consortium, services, and companionship. Plaintiffs sought $500,000 in damages. On August 19, 1993, Telectronics Pacing Systems, Inc. moved for summary judgment on plaintiffs' claims as they pertained to the Defibrillator and the Connectors on the ground that those claims were preempted by federal law, pursuant to 21 U.S.C. §360k(a), which states as follows:

> Except as provided in subsection (b) of this section, no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement —
>
> (1) which is different from, or in addition to,

> any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

On December 14, 1993, this Court issued an Opinion and Order granting defendant Telectronics Pacing Systems, Inc.'s motion for partial summary judgment. In that Opinion and Order, the Court set forth its conclusion that plaintiffs' Ohio law causes of action related to the Defibrillator and the Connectors were preempted under 21 U.S.C. §360k(a). The Court concluded that the Ohio statutory and common law causes of action are requirements that are different from and in addition to the requirements applicable under the Medical Device Amendments of the Federal Drug Act. 21 U.S.C. §360k(a)(1). The Court also concluded that the state laws relate to the safety or effectiveness of the device. 21 U.S.C. §360k(a)(2). The Court dismissed plaintiffs' state law claims related to the Defibrillator and the Connectors. The Court did not consider plaintiffs' claims as they related to the Leads, because defendants had not moved for summary judgment on those claims.

Pursuant to an Order dated February 23, 1994, the Court granted plaintiffs' motion to file an amended complaint. In that amended complaint, plaintiffs assert the same causes of action as those that were raised in the initial complaint. Plaintiff Ada Martin asserts claims under §§ 2307.74, .75, .76, .77, and .78 with respect to the Leads and the Adapter. In addition, Mrs. Martin reasserts the claims related to the Defibrillator and the Connectors that the Court dismissed pursuant to the December

14, 1993 Opinion and Order. Plaintiff Harold Martin asserts a claim for loss of services, consortium, and companionship.

Defendants move for summary judgment on the ground that the Leads and the Adapter are components of the Guardian 4210 System and that the entire system is an investigational device under the Medical Device Amendments. Accordingly, defendants argue, 21 U.S.C. §360k(a) preempts plaintiffs' claims with respect to the Leads and the Adapter to the same extent as it preempts the claims related to the Defibrillator and the Connectors.

Plaintiffs concede that the Leads and the Adapter are components of the Guardian 4210 System and that the system is an investigational device under the Medical Device Amendments. Plaintiffs' Memorandum Contra, p.3. Plaintiffs argue, in essence, that the Courts conclusions in its December 14, 1993 opinion and Order are erroneous and that the Court should deny defendants' motion for summary judgment on plaintiffs' claims related to the Leads and the Adapter and reinstate plaintiffs' dismissed claims related to the Leads and the Defibrillator. Accordingly, the issue before the Court is identical to the one that the Court resolved in the December 14, 1993 Opinion and Order. The Court views plaintiffs' memorandum contra defendants' motion for summary judgment and defendants' reply memorandum as supplemental to those the Court considered in its earlier Opinion and Order. Because the issue before the Court is the same as that addressed in its December 14, 1993 Opinion and Order, the Court will consider in this Memorandum and Order whether plaintiffs have established that the Court erred in its earlier decision. Plaintiffs again argue that the Ohio statutes and common law upon which they base their claims are not the type of "requirements" that are

preempted under 21 U.S.C. §360k(a). Plaintiffs base their argument upon the language of 21 C.F.R. §808.1(d)(1), which states that the Medical Device Amendments do not preempt state or local requirements of general applicability where the state or local requirements relate to products in addition to medical devices. Plaintiffs contend that their causes of action are based upon state law requirements that are generally applicable to most products and are not restricted in applicability to medical devices. *see Mulligan v. Pfizer. Inc.*, Case No. C-1-92-672, U.S. Dist. LEXIS 4558 (S.D. Ohio April 14, 1994) The Court observes that the provision of the Code of Federal Regulations upon which plaintiffs rely also provides as follows:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act.

21 C.F.R. §808.1(b). Accordingly, plaintiffs may only base claims upon Section 2307 of the Ohio Revised Code and Ohio common law to the extent that their causes of action are based upon requirements of general applicability and the FDA has not established regulations regarding the manufacture, design, and use of the Guardian 4210 System.

Plaintiffs also rely extensively upon a recent decision from this District, *Mulligan, supra* (Spiegel, J.), and another from the District of Colorado, *Oja v. Howemedica, Inc.*, Case No. 93-C-858, slip op. (D.Colo. March 23, 1994). The *Mulligan* and *Oja* decisions were issued after this Court issued the December 14, 1993 Opinion and Order.

This Court does not take issue with any of the conclusions reached by the courts in those cases. The Court observes, however, that neither decision addresses the issue before the Court. The devices in question in *Mulligan* and *Oja* were not Class III devices, as is the Guardian 4210 System. The courts, therefore, did not determine whether the FDA's requirements for Class III investigational devices constitute "specific counterpart regulations," such that state or local requirements are preempted pursuant to 21 U.S.C. §360k(a) as interpreted by 21 C.F.R. §808.1(b). In its December 14, 1993 Opinion and Order, this Court concluded that the relevant state law causes of action are preempted. The *dicta* in the *Oja* decision suggests strongly that the court in that case concurs with this Court's conclusion:

> Class III devices are subject to formal and extensive pre-market approval requirements that qualify as "specific requirements applicable to a particular device" for preemption purposes. *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422 and n.3 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993); *King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993).

Oja, supra, at p.7. While the Mulligan court did not discuss the distinctions between Class III and non-Class III devices, this Court finds nothing in the *Mulligan* decision that suggests that the conclusion therein applies equally to all classes of devices.

For the reasons set forth in this Court's December 14, 1993 Opinion and Order, together with those set forth herein, the Court concludes that all of the causes of action asserted by the plaintiffs in their amended complaint are preempted by federal law.

Appendix B

Accordingly, defendants' April 29, 1994 motion for summary judgment is hereby **GRANTED**. This case is **DISMISSED** in its entirety. The Clerk of this Court is directed to enter **JUDGMENT** in favor of the defendants.

IT IS SO ORDERED.

s/ Sandra S. Beckwith
Sandra S. Beckwith
United States District Judge

Appendix B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

Case No: C2-93-580
Judge Beckwith
Magistrate Judge Abel

Ada M. Martin, et al.,

Plaintiffs,

v.

Telectronics Pacing Systems, Inc., et al.,

Defendants.

JUDGMENT IN A CIVIL CASE

[ ] Jury Verdict. This action came before the Court for a trial by jury. The issues have been tried and the jury has rendered its verdict.

[X] Decision by Court. This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered.

IT IS ORDERED AND ADJUDGED that pursuant to the September 7, 1994 Memorandum and Order by Judge Beckwith granting defendants' April 29, 1994 motion for summary judgment, this case is **DISMISSED. JUDGMENT** is entered in favor of the defendants.

Appendix B

September 7, 1994
Date

KENNETH J. MURPHY
Clerk

s/ Michael Carey
(By) Deputy Clerk
Michael Carey

APPENDIX C — OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO, EASTERN DIVISION FILED DECEMBER 14, 1993

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

Civil Action C-2-93-580

Judge Beckwith

Magistrate Judge Abel

Ada M. Martin, et al.,

Plaintiffs

v.

Telectronics Pacing Systems, Inc., et al.

Defendants

OPINION AND ORDER

Plaintiffs Ada and Harold Martin initiated this action in the Court of Common Pleas of Franklin County, Ohio on May 14, 1993, alleging numerous state-law causes of action arising from Ada Martin's use of certain medical devices designed and manufactured by Telectronics Pacing Systems, Inc. (hereinafter referred to as "Telectronics") or one of the Doe defendants named in the Complaint. On June 10, 1993, Telectronics removed the action to this Court. This matter is presently before

the Court for consideration of plaintiffs' motion to remand and cross motions for summary judgment.

Background

On March 31, 1992, doctors surgically implanted in plaintiff Ada Martin a cardioverter defibrillator (hereinafter referred to as the "Defibrillator"), Model 040-106 defibrillator leads (hereinafter referred to as the "Model 040-106 Leads"), and Model 033-572 leads (hereinafter referred to as the "Model 033-572 Leads" and together with the Model 040-106 Leads as the "Leads"), which were manufactured, designed, and/or supplied by electronics or one or more of the fifteen Doe defendants named in this action. The parties agree that the Defibrillator and the Model 040-106 Leads were not approved by the Federal Food and Drug Administration (hereinafter referred to as the "FDA") and were undergoing investigative study. The FDA had authorized the marketing of the Model 033-572 Leads. The parties further agree that Ada Martin had consented to participate in the study of the Defibrillator and the Model 040-106 Leads.

On November 19, 1992, Ada Martin underwent a second surgical procedure during which physicians removed the Defibrillator and the Leads and replaced them with another medical device. Ada Martin claims that the Defibrillator and the Leads were defective and that she was injured as a result of the defects and the resulting necessity of a second invasive surgical procedure. Among the alleged injuries are trauma to her body structure, permanent physical pain, anxiety, mental distress, loss of enjoyment of life, inability to perform ordinary activities, and physical impairment. Plaintiff claims that she will incur reasonable medical expenses and lost income into the indefinite future. Plaintiff Harold Martin, Ada Martin's spouse, claims to

have suffered loss of services, companionship, and consortium and alleges that he will suffer such loss into the indefinite future. Plaintiffs pray for damages in the amount of $500,000.00, together with interest and costs. Ada Martin asserts five causes of action arising under Section 2307 of the Ohio Revised Code ("O.R.C."). Specifically, she asserts that the Defibrillator and the Leads were defective in manufacture or construction in that they deviated from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units (O.R.C. §2307.74). She also alleges that the Defibrillator and the Leads were defective in design, because the risks associated with their design exceeded the benefits of that design (O.R.C. §2307.75). Pursuant to her third cause of action, plaintiff Ada Martin alleges that defendants provided inadequate warnings and instructions before and/or after the initial sale of the Defibrillator and the Leads (O.R.C. §3207.76). She further alleges that the Defibrillator and the Leads failed to conform to express representations of material facts concerning the character, quality, and/or safety of the products (O.R.C. §2307.77). Finally, plaintiff Ada Martin alleges that the defendants are liable for damages arising from her injuries as suppliers of defective products (O.R.C. §2307.78). Plaintiff Harold Martin asserts one cause of action based on Ohio common law pursuant to which he alleges the loss of his wife's services, companionship, and consortium.

The Motion to Remand

In its Notice of Removal, filed on June 10, 1993, defendant Telectronics cites two bases for this Court's exercise of jurisdiction over the subject matter of this action. First, defendant notes that diversity of citizenship exists between plaintiffs, who are citizens of Ohio, and Telectronics, which is a

citizen of Colorado for purposes of establishing diversity. Plaintiffs concede that diversity currently exists in this action; although, they argue that diversity may be destroyed by the identification of one or more of the Doe defendants. Telectronics also asserts federal question jurisdiction on the ground that plaintiffs' state law causes of action are preempted by federal law. Specifically, defendant asserts that the Medical Device Amendments to the Food, Drug and Cosmetic Act (hereinafter referred to together as the "Act") expressly preempt all state law remedies in the areas governed by the Act.

Plaintiffs move to remand on the ground that their state law causes of action are not preempted by the Act. They concede, however, that diversity is currently present. The Court notes that, for purposes of establishing diversity jurisdiction, the citizenship of Doe defendants is not considered. Section 1441 of Title 28, United States Code, provides, in pertinent part, as follows:

> (a) Except as otherwise provided by Act of Congress, any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district court of the United States for the district and division embracing the place where such action is pending. For purposes of removal under this chapter, the citizenship of defendants sued under fictitious names shall be disregarded.

Clearly, defendant's removal of this action was permissible in spite of the fact that plaintiffs had named Doe defendants. This

Appendix C

Court may properly exercise jurisdiction over the subject matter of this dispute, the parties arguments concerning preemption notwithstanding. Plaintiffs' motion to remand is **DENIED**.

The Motions for Summary Judgment

While the Court need not resolve the parties' dispute concerning preemption in order to decide the plaintiffs' motion to remand this action, that dispute is also the focus of the parties' motions for summary judgment. On August 19, 1993, Telectronics moved for partial summary judgment. The basis for Telectronics' motion is that plaintiffs' claims related to the Defibrillator and the Model 040-106 Leads are preempted by federal law. By way of a response to defendant's motion, plaintiffs filed a motion for partial summary judgment, seeking a declaration that their state law claims are not preempted.

The Summary Judgment Standard

Rule 56 (c) provides that summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." The purpose of the procedure is not to resolve factual issues, but to determine if there are genuine issues of fact to be tried. *Lashlee v. Sumner*, 570 F.2d 107, 111 (6th Cir. 1978). Summary judgment, therefore, will not lie if the dispute about a material fact is genuine, "that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986).

In a motion for summary judgment, the moving party bears

the "burden of showing the absence of a genuine issue as to any material fact, and for these purposes, the [evidence submitted] must be viewed in the light most favorable to the opposing party." *Adickes v. S. H. Kress & Co.*, 398 U.S. 144, 157 (1970); *accord, Adams v. Union Carbide Corp.*, 737 F.2d 1453, 1455-56 (6th Cir.), *cert. denied*, 469 U.S. 1062 (1984). The moving party is entitled to summary judgment "where it is quite clear what the truth is and where there are no unexplained gaps in documents submitted by the moving party pertinent to material issues of fact." *Poller v. Columbia Broadcasting System, Inc.*, 368 U.S. 464, 467 (1962); *accord, County of Oakland v. Berkley*, 742 F.2d 289, 297 (6th Cir. 1984); *Adickes*, 398 U.S. at 157-60; *Smith v. Hudson*, 600 F.2d 60, 65 (6th Cir.), *cert. dismissed*, 444 U.S. 986 (1979).

If the moving party meets its burden and if adequate time for discovery has been provided, the opposing party is required to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof as well. *Celotex Corp. v. Catrett*, 477 U.S. 317, 326 (1986). The mere existence of a scintilla of evidence in support of the opposing party's claim will be insufficient; plaintiff "must set forth specific facts showing that there is a genuine issue for trial." *Davis v. Robbs*, 794 F.2d 1129, 1130 (6th Cir.), *cert. denied*, 479 U.S. 992 (1986) (emphasis in original).

Rule 56(e) provides as follows:

> When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of his pleading, but his

> response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If he does not so respond, summary judgment, if appropriate, shall be entered against him.

Therefore, a party may not rest on the allegations contained in his pleadings to overcome a properly supported motion for summary judgment. *First National Bank v. Cities Service Co.*, 391 U.S. 253; 259 (1968) (footnote omitted).

Decision

Article VI of the United States Constitution provides that "the laws of the United States shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." Art. VI, cl. 2. It is well-settled that "state law that conflicts with federal law is without effect." *Cippollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 120 L. Ed.2d 407, 422 (1992) (citing *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). "Consideration of issues arising under the Supremacy Clause start[s] with the assumption that the historic police powers of the States are] not to be superseded by . . . Federal Act unless that is] the clear and manifest purpose of Congress." *Id.* (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

"Congress' intent may be explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Id.* at 422-23 (citing *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (internal quotation marks omitted)). Even in the absence of an express congressional mandate, federal law may preempt

state law with which it actually conflicts. *See Pacific Gas & Electric Co. v. Energy Resources Conservation and Development Commission*, 461 U.S. 190, 204 (1983). Preemption will also result when federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the states to supplement it. *Cippollone*, 120 L. Ed.2d at 423 (citing *Fidelity Federal Savings & Loan Association v. De la Cuesta*, 458 U.S. 141, 153 (1977) (internal quotation marks and citation omitted)).

When Congress has included a preemption provision in an enactment, the Court need not look beyond that provision to determine the preemptive scope of the enactment. *Cipollone*, 120 L. Ed.2d at 423 (citing *California Federal Savings & Loan Association v. Guerra*, 479 U.S. 272, 282 (1987) (opinion of Marshall, J.)). "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Cippollone*, 120 L. Ed.2d at 423. Accordingly, when a preemption provision is included in the enactment, the Court need only "identify the domain expressly pre-empted" by that provision. *Id.* The Court must construe the provision in light of the presumption against the preemption of state police power regulations. *Id.* at 424.

The preemption provision in question in this action is found at 21 U.S.C. §360k(a), which states as follows:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

The preemptive scope of 21 U.S.C. §360k(a) is extremely broad, even when examined in light of the presumption against preemption. Congress explicitly preempted any requirement relating to the safety or effectiveness of a medical device in addition to those set forth in the Act. Accordingly, the Court must determine whether the Ohio statutory causes of action asserted by plaintiff Ada Martin are requirements relating to the safety or effectiveness of the Defibrillator and the Model 040-106 Leads.

Plaintiff Ada Martin asserts five causes of action arising under O.R.C. chapter 2307. Section 2307.74, in conjunction with §2307.73, imposes liability upon the manufacturer of a defective product. Section 2307.74 identifies as a defective product one that deviates in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units. Section 2307.75 establishes liability against the manufacturer of a product that is defective in design or formulation. Section 2307.76 provides that a manufacturer may be liable for a defect resulting from inadequate warning and instruction. Similarly, §2307.77 establishes the liability of a manufacturer whose product does not conform to a representation made by that manufacturer.

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Each of the provisions contained in O.R.C. §§2307.74-.77 relates to the safety or effectiveness of a product. Plaintiffs argue that those provisions are not requirements and, therefore, are not preempted by the Act. The Supreme Court has stated, however, that the obligation to pay damages is itself a method of governing conduct and, thus, a requirement. *Cippollone,* 120 L. Ed.2d at 425-26. The Court noted that tort damage actions "are premised on the existence of a legal duty and it is difficult to say that such actions do not impose requirements or prohibitions." *Id.* at 426 (internal quotation marks and citation omitted). The Court concludes, therefore, that plaintiff Ada Martin's first four causes of action are preempted under 21 U.S.C. §360k(a).

Pursuant to her fifth cause of action, plaintiff Ada Martin attempts to impose liability upon defendant as a supplier of the Defibrillator and the Leads under O.R.C. §2307.78. Plaintiff incorporates the allegations of her four previous causes of action. Inasmuch as her plaintiff's fifth cause of action also relates to the safety and effectiveness of the Defibrillator, the Court concludes that it is preempted by the Act.

This Court's conclusions are consistent with those reached by the Seventh Circuit Court of Appeals in *Slater v. Optical Radiation Corporation,* 961 F.2d 1330 (7th Cir.), *cert. denied,* 113 S.Ct. 327 (1992). The *Slater* court determined that 21 U.S.C. §360k(a) dictated the preemption of state law tort claims related to the design of an intraocular lens that was, like the Defibrillator and the Model 040-106 Leads, an investigational device for purposes of the application of the Act. The court concluded that the plaintiff's claims were preempted but noted that the preemptive scope of the Act is limited. *Id.* at 1334. The court stated, for example, that causes of action related to improper implantation or removal of the device, contamination

of the device by bacteria or fungi, or failure to obtain the patient's informed consent would not be preempted. *Id.*

Plaintiffs argue that the *Slater* case is distinguishable from this action. While plaintiffs concede the similarity between some of their claims and those asserted by the plaintiff in *Slater*, they argue that their claims relating to defendant's alleged deviation from its own specifications are unlike any raised in *Slater* and are not preempted by the Act; The Court notes that the *Slater* court did not attempt to define the universe of preempted claims. Plaintiffs' claim of deviation from specifications undeniably relates to the safety and effectiveness of the Defibrillator and the Leads, and the Court determines that plaintiffs cannot maintain that cause of action in the face of 21 U.S.C. §360k(a).

Plaintiff Harold Martin asserts only one claim. He alleges that, as a result of defendant's actions as alleged in the first five causes of action, he has lost his wife's services, companionship, and consortium. Plaintiff Harold Martin may only recover damages for his loss if defendant intentionally or negligently injured his wife, thereby causing an injury to him. *See,e.g., Bowen v. Kil-Kare. Inc.*, 63 Ohio St.3d 84, 90 (1992). Harold Martin makes no allegations, however, apart from those asserted by his wife. The Court has determined that all of Ada Martin's allegations relate to the safety or effectiveness of the Defibrillator and the Leads and that the claims based upon those allegations are preempted pursuant to 21 U.S.C. §360k(a). The Court concludes that Harold Martin's common law cause of action also is preempted as attempting to impose upon defendant the same requirements relating to safety and effectiveness as do the claims asserted by his wife.

Plaintiffs argue that Congress could not have intended to

leave injured persons without a remedy. The Court notes that some remedies are available under the Act itself. The Court also notes, however, to the extent that some injuries may go unredressed as a result of preemption, Congress requires that a manufacturer of an investigational device obtain the informed consent of any participant in the investigation of the device. 21 U.S.C. §360j(g)(3)(D). Failure to obtain such consent is a violation of the Act. Accordingly, an injured party has not been subjected to a risk without prior knowledge that the device in question was not, and may never be, thoroughly tested and approved by the FDA.

Conclusion

For the foregoing reasons, plaintiffs' motion to remand is hereby **DENIED**. Plaintiffs' motion for partial summary judgment is also hereby **DENIED**. Defendant Telectronics Pacing Systems, Inc.'s motion for partial summary judgment is hereby **GRANTED**. All of plaintiffs' claims against defendant Telectronics relating to the Defibrillator and the Model 040-106 Leads are dismissed. Because defendant Telectronics has not sought summary judgment with respect to plaintiffs' claims as they relate to the Model 033-572 Leads, this action will proceed on those claims only.

IT IS SO ORDERED.

s/ Sandra S. Beckwith
Sandra S. Beckwith
United States District Judge

APPENDIX D — RELEVANT PROVISIONS OF THE CONSTITUTION OF THE UNITED STATES, STATUTES AND REGULATIONS

UNITED STATES CONSTITUTION

ARTICLE I, SECTION 8

* * *

To regulate commerce with foreign Nations, and among the several States, and with the Indian Tribes. . . .

ARTICLE VI

* * *

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

* * *

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AMENDMENT VII

In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of the common law.

(Effective 1791)

AMENDMENT IX

The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.

(Effective 1791)

AMENDMENT X

The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

(Effective 1791)

Appendix D

OHIO REVISED CODE

§ 2307.71 Definitions.

As used in sections 2307.71 to 2307.80 of the Revised Code:

(A) "Claimant" means other of the following:

(1) A person who asserts a product liability claim or on whose behalf such a claim is asserted;

(2) If a product liability claim is asserted on behalf of the surviving spouse, children, parents, or other next of kin of a decedent or on behalf of the estate of a decedent, whether as a claim in a wrongful death action under Chapter 2125, of the Revised Code or as a survivorship claim, whichever of the following is appropriate:

(a) The decedent, if the reference is to the person who allegedly sustained harm or economic loss for which, or in connection with which, compensatory damages or punitive or exemplary damages are sought to be recovered;

(b) The personal representative of the decedent or the estate of the decedent, if the

reference is to the person who is asserting or has asserted the product liability claim.

(B) "Economic loss" means direct, incidental, or consequential pecuniary loss including, but not limited to, damage to the product in question, and nonphysical damage to property other than that product. Harm is not "economic loss."

(C) "Environment" means navigable waters, surface water, ground water, drinking water supplies, land surface, subsurface strata, and air.

(D) "Ethical drug" means a prescription drug that is prescribed or dispensed by a physician or any other person who is legally authorized to prescribe or dispense a prescription drug.

(E) "Ethical medical device" means a medical device that is prescribed, dispensed, or implanted by a physician or any other person who is legally authorized to prescribe, dispense, or implant a medical device and that is regulated under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C 301-392, as amended.

(F) "Foreseeable risk" means a risk of harm that satisfies both of the following:

(1) It is associated with an intended or reasonably foreseeable use, modification, or alteration of a product in question;

(2) It is a risk that the manufacturer in question should recognize while exercising both of the following:

(a) The attention, perception, memory, knowledge, and intelligence that a reasonable manufacturer should possess;

(b) Any superior attention, perception, memory, knowledge, or intelligence that the manufacturer in question possesses.

(G) "Harm" means death, physical injury to person, serious emotional distress, or physical damage to property other than the product in question. Economic loss is not "harm."

(H) "Hazardous or toxic substances" include, but are not limited to, hazardous waste as defined in section 3734.01 of the Revised Code, hazardous waste as specified in the rules of the director of environmental protection pursuant to division (A) of section 3734.12 of the Revised Code, hazardous substances as defined in section 3716.01 of the Revised Code, and hazardous substances, pollutants, and contaminants as defined in or by regulations adopted pursuant to the

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"Comprehensive Environmental Response, Compensation, and Liability Act of 1980," 94 Stat. 2767, 42 U.S.C. 9601, as amended.

(I) "Manufacturer" means a person engaged in a business to design, formulate, produce, create, make, construct, assemble, or rebuild a product or a component of a product.

(J) "Person" has the same meaning as in division (C) of section 1.59 of the Revised Code and also includes governmental entities.

(K) "Physician" means a person who is licensed to practice medicine and surgery or osteopathic medicine and surgery by the state medical board.

(L)(1) "Product" means, subject to division (L)(2) of this section, any object, substance, mixture, or raw material that constitutes tangible personal property and that satisfies all of the following:

(a) It is capable of delivery itself, or as an assembled whole in a mixed or combined state, or as a component or ingredient;

(b) It is produced, manufactured, or supplied for introduction into trade or commerce;

(c) It is intended for sale or lease to persons for commercial or personal use.

(2) "Product" does not include human tissue, blood, or organs.

(M) "Product liability claim" means a claim that is asserted in a civil action and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following:

(1) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;

(2) Any warning or instruction, or lack of warning or instruction, associated with that product;

(3) Any failure of that product to conform to any relevant representation or warranty.

(N) "Representation" means an express representation of a material fact concerning the character, quality, or safety of a product.

(O)(1) "Supplier" means, subject to

division (O)(1) of this section, either of the following:

(a) A person that, in the course of a business conducted for the purpose, sells, distributes, leases, prepares, blends, packages, labels, or otherwise participates in the placing of a product in the stream of commerce;

(b) A person that, in the course of a business conducted for the purpose, installs, repairs, or maintains any aspect of a product that allegedly causes harm.

(2) "Supplier" does not include any of the following:

(a) A manufacturer;

(b) A seller of real property;

(c) A provider of professional services who, incidental to a professional transaction the essence of which is the furnishing of judgment, skill, or services, sells or uses a product;

(d) Any person who acts only in a financial capacity with respect to the sale of a product, or who leases a product under a lease arrangement in which the selection,

possession, maintenance, and operation of the product are controlled by a person other than the lessor.

(P) "Unavoidably unsafe" means that, in the state of technical, scientific, and medical knowledge at the time a product in question left the control of its manufacturer, an aspect of that product was incapable of being made safe.

§ 2307.72 Damages recoverable on product liability claim; environmental damage.

(A) Any recovery of compensatory damages based on a product liability claim is subject to sections 2307.71 to 2307.79 of the Revised Code.

(B) Any recovery of punitive or exemplary damages in connection with a product liability claim is subject to sections 2307.71 to 2307.80 of the Revised Code.

(C) Any recovery of compensatory damages for economic loss based on a claim that is asserted in a civil action, other than a product liability claim, is not subject to sections 2307.71 to 2307.79 of the Revised Code, but may occur under the common law of this state or other applicable sections of the Revised Code.

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(D)(1) Sections 2307.71 to 2307.80 of the Revised Code do not supersede, modify, or otherwise affect any statute, regulation, or rule of this state or of the United States, or the common law of this sate or of the United States, that relates to liability in compensatory damages or punitive or exemplary damages for injury, death, or loss to person or property, or to relief in the form of the abatement of a nuisance, civil penalties, cleanup costs, cost recovery, an injunction or temporary restraining order, or restitution, that arises, in whole or in part, from contamination or pollution of the environment or a threat of contamination or pollution of the environment, including contamination or pollution or a threat of contamination or pollution from hazardous or toxic substances.

(2) Consistent with the Rules of Civil Procedure, in the same civil action against the same defendant or different defendants, a claimant may assert both of the following:

(a) A product liability claim, including a claim for the recovery of punitive or exemplary damages in connection with a product liability claim;

(b) A claim for the recovery of compensatory damages or punitive or exemplary damages for injury, death, or loss

to person or property, or for relief in the form of the abatement of a nuisance, civil penalties, cleanup costs, cost recovery, an injunction or temporary restraining order, or restitution, that arises, in whole or in part, from contamination or pollution of the environment or a threat of contamination or pollution of the environment, including contamination or pollution or a threat of contamination or pollution from hazardous or toxic substances.

§ 2307.3 When manufacturer is liable for compensatory damages; evidence of defect.

(A) A manufacturer is subject to liability for compensatory damages based on a product liability claim only if the claimant establishes, by a preponderance of the evidence, both of the following:

(1) Subject to division (B) of this section, the product in question was defective in manufacture or construction as described in section 2307.74 of the Revised Code, was defective in design or formulation as described in section 2307.75 of the Revised Code, was defective due to inadequate warning or instruction as described in section 2307.76 of the Revised Code, or was defective because it did not conform to a representation made by its manufacturer as described in section 2307.77 of the Revised Code;

(2) A defective aspect of the product in question as described in division (A)(1) of this section was a proximate cause of harm for which the claimant seeks to recover compensatory damages.

(B) If a claimant is unable because a product in question was destroyed to establish by direct evidence that the product in question was defective or if a claimant otherwise is unable to establish by direct evidence that a product in question was defective, then, consistent with the Rules of Evidence, it shall be sufficient for the claimant to present circumstantial or other competent evidence that establishes, by a preponderance of the evidence, that the product in question was defective in any one of the four respects specified in division (A)(1)of this section.

§ 2307.74 When product is defective in manufacture or construction.

A product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards. A product may be defective in

manufacture or construction as described in this section even though its manufacturer exercised all possible care in its manufacture or construction.

§ 2307.75 When product is defective in design or formulation.

(A) Subject to divisions (D), (E), and (F) of this section, a product is defective in design or formulation if either of the following applies:

(1) When it left the control of its manufacturer, the foreseeable risks associated with its design or formulation as determined pursuant to division (B) of this section exceeded the benefits associated with that design or formulation as determined pursuant to division (C) of this section;

(2) It is more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

(B) The foreseeable risks associated with the design or formulation of a product shall be determined by considering factors including, but not limited to, the following:

(1) The nature and magnitude of the risks of harm associated with that design or formulation in light of the intended and

reasonably foreseeable uses, modifications, or alterations of the product;

(2) The likely awareness of product users, whether based on warnings, general knowledge, or otherwise, of those risks of harm;

(3) The likelihood that that design or formulation would cause harm in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product;

(4) The extent to which that design or formulation conformed to any applicable public or private product standard that was in effect when the product left the control of its manufacturer.

(C) The benefits associated with the design or formulation of a product shall be determined by considering factors including, but not limited to, the following:

(1) The intended or actual utility of the product, including any performance or safety advantages associated with that design or formulation;

(2) The technical and economic feasibility, when the product left the control of its manufacturer, of using an alternative design or formulation;

(3) The nature and magnitude of any foreseeable risks associated with such an alternative design or formulation.

(D) An ethical drug or ethical medical device is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the ethical drug or ethical medical device provides adequate warning and instruction under section 2307.76 of the Revised Code concerning that unavoidably unsafe aspect.

(E) A product is not defective in design or formulation if the harm for which the claimant seeks to recover compensatory damages was caused by an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability and which is recognized by the ordinary person with the ordinary knowledge common to the community.

(F) A product is not defective in design or formulation if, at the time the product left the control of its manufacturer, a practical and technically feasible alternative design or formulation was not available that would have prevented the harm for which the claimant seeks to recover compensatory damages without substantially impairing the

usefulness or intended purpose of the product, unless the manufacturer acted unreasonably in introducing the product into trade or commerce.

§ 2307.76 When product is defective due to inadequate warning or instruction.

(A) Subject to divisions (B) and (C) of this section, a product is defective due to inadequate warning or instruction if either of the following applies:

(1) It is defective due to inadequate warning or instruction at the time of marketing if, when it left the control of its manufacturer, both of the following applied:

(a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;

(b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

(2) It is defective due to inadequate post-marketing warning or instruction if, at a relevant time after it left the control of its manufacturer, both of the following applied:

(a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;

(b) The manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

(B) A product is not defective due to lack of warning or instruction or inadequate warning or instruction as a result of the failure of its manufacturer to warn or instruct about an open and obvious risk or a risk that is a matter of common knowledge.

(C) An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or

other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

§ 2307.77 Conformance to representa-tion.

A product is defective if it did not conform when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation.

§ 2307.78 When a supplier is liable for compensatory damages.

(A) Subject to divisio. (B) of this section, a supplier is subject to liability for compensatory damages based on a product liability claim only if the claimant establishes, by a preponderance of the evidence, that either of the following applies:

(1) The supplier in question was negligent and that negligence was a proximate cause of harm for which the claimant seeks to recover compensatory damages;

(2) The product in question did not conform, when it left the control of the supplier in question, to a representation made by that supplier, and that representation and the failure to conform to it were a proximate cause of harm for which the claimant seeks to recover compensatory damages. A supplier is subject to liability for such a representation and the failure to conform to it even though the supplier did not act fraudulently, recklessly, or negligently in making the representation.

(B) A supplier of a product is subject to liability for compensatory damages based on a product liability claim under sections 2307.71 to 2307.77 of the Revised Code, as if it were the manufacturer of that product, if the manufacturer of that product is or would be subject to liability for compensatory damages based on a product liability claim under sections 2307.71 to 2307.77 of the Revised Code and any of the following supplies:

(1) The manufacturer of that product is not subject to judicial process in this state;

(2) The claimant will be unable to enforce a judgment against the manufacturer of that product due to actual or asserted insolvency of the manufacturer;

(3) The supplier in question owns or, when it supplied that product, owned, in whole or in part, the manufacturer of that product;

(4) The supplier in question is owned or, when it supplied that product, was owned, in whole or in part, by the manufacturer of that product;

(5) The supplier in question created or furnished a manufacturer with the design or formulation that was used to produce, create, make, construct, assemble, or rebuild that product or a component of that product;

(6) The supplier in question altered, modified, or failed to maintain that product after it came into the possession of, and before it left the possession of, the supplier in question, and the alteration, modification, or failure to maintain that product rendered it defective;

(7) The supplier in question marketed that product under its own label or trade name;

(8) The supplier in question failed to respond timely and reasonably to a written request by or on behalf of the claimant to disclose to the claimant the name and address of the manufacturer of that product.

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§ 2307.79 Compensatory damages for economic loss.

(A) If a claimant is entitled to recover compensatory damages for harm from a manufacturer in accordance with section 2307.73 of the Revised Code or from a supplier in accordance with division (B) of section 2307.78 of the Revised Code, the claimant may recover from the manufacturer or supplier in question, in that action, compensatory damages for any economic loss that proximately resulted from the defective aspect of the product in question.

(B) If a claimant is entitled to recover compensatory damages for harm from a supplier in accordance with division (A) of section 2307.78 of the Revised Code, the claimant may recover from the supplier in question, in that action, compensatory damages for any economic loss that proximately resulted from the negligence of that supplier or from the representation made by that supplier and the failure of the product in question to conform to that representation.

§ 2307.80 Punitive or exemplary damages.

(A) Subject to division (C) of this section, punitive or exemplary damages shall not be awarded against a manufacturer or supplier in question in connection with a product liability claim unless the claimant

establishes, by clear and convincing evidence, that harm for which he is entitled to recover compensatory damages in accordance with section 2307.73 or 2307.78 of the Revised Code was the result of misconduct of the manufacturer or supplier in question that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question. The fact by itself that a product is defective does not establish a flagrant disregard of the safety of persons who might be harmed by that product.

(B) Whether the trier of fact is a jury or the court, if the trier of fact determines that a manufacturer or supplier in question is liable for punitive or exemplary damages in connection with a product liability claim, the amount of those damages shall be determined by the court. In determining the amount of punitive or exemplary damages, the court shall consider factors including, but not limited to, the following:

(1) The likelihood that serious harm would arise from the misconduct of the manufacturer or supplier in question;

(2) The degree of the awareness of the manufacturer or supplier in question of that likelihood;

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(3) The profitability of the misconduct to the manufacturer or supplier in question;

(4) The duration of the misconduct and any concealment of it by the manufacturer or supplier in question;

(5) The attitude and conduct of the manufacturer or supplier in question upon the discovery of the misconduct and whether the misconduct ha terminated;

(6) The financial condition of the manufacture or supplier in question;

(7) The total effect of other punishment imposed or likely to be imposed upon the manufacturer or supplier in question as a result of the misconduct including awards of punitive or exemplary damage to persons similarly situated to the claimant and the severity of criminal penalties to which the manufacturer or supplier in question has been or is likely to be subjected.

(C) If a claimant alleges in a product liability claim that a drug caused harm to him, the manufacturer of the drug shall not be liable for punitive or exemplary damages in connection with that product liability claim if the drug that allegedly caused the harm was manufactured and labeled in relevant and material respects in accordance with the

terms of an approval or license issued by the federal food and drug administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. 301-392, as amended, or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. 201-300cc-15, as amended, unless it is established, by a preponderance of the evidence, that the manufacturer fraudulently and in violation of applicable regulations of the food and drug administration withheld from the food and drug administration information known to be material and relevant to the harm that the claimant allegedly suffered or misrepresented to the food and drug administration information of that type. For purposes of this division, "drug has the meaning given to that term In section 1201(g)(1) of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C 301-392, as amended.

21 U.S.C. § 360k

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the

requirement would not cause the device to be in violation of any applicable requirement under this chapter.

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21 U.S.C. § 360h(d)

Effect on Other Liability

Compliance with an order [requiring a manufacturer to repair, replace, or provide reimbursement for expenses relating to an unsafe device] issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

21 C.F.R. § 808.1(d)

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device

different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. § 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521 (a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and ' the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices . . .

APPENDIX E — EXCERPTS OF SEVENTH AMENDMENT LAW REVIEW ARTICLE FOUND IN VOLUME 57 OF THE MINNESOTA LAW REVIEW

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2. *The Frustration of Unwise Legislative and Administrative Policies.*

The paper money and British debt claims were the most prominently discussed civil jury trial issues during the ratification debates. There were others, however, which proceeded on the same general theme of the utilization of the jury because of its presumed willingness to act "lawlessly." Only fragments of these arguments survive, but enough remains to furnish support for the proposition that the concerns of the antifederalists for the protection of civil jury trials went beyond issues that, as with paper money and the collection of British debts, might be regarded as peculiar to the immediate post-Revolutionary years.

In his Number 83 of *The Federalist*, which is devoted entirely to the civil jury trial question, Hamilton examined at some length one of the many objections that were made by antifederalists to the absence of a guarantee of civil jury trial: "It has been observed, that trial by jury is a safeguard against an oppressive exercise of the power of taxation. This observation deserves to be canvassed."[183] Were it not for this unequivocal

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183. THE FEDERALIST No. 83, at 563 (J. Cooke ed. 1961). In reply to the argument that the right of civil jury trial was desirable in order to prevent the imposition of unjust taxes by the government, Hamilton replied rather aridly that the jury would be helpless because: (1) "It is evident that it can have no influence upon the legislature, in regard to the *amount* of the taxes to be laid, to the *objects* upon which they are to be imposed, or to the *rule* by which they are to be apportioned . . ." (emphasis in original); (2) taxes were usually levied in most

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indication of the antifederalist interest in the utilization of juries in tax collection cases, one would be hard pressed — on the basis of other materials — to assert that the matter was given any but rather indirect attention by antifederalist. Yet other suggestions of the antifederalist argument as to the taxing and other legislative powers can be found.

At one point in a speech in the Virginia ratification convention, James Monroe argued against the broad powers given Congress in the absence of a bill or fights. To illustrate his argument he pointed to the broad powers of taxation given to Congress and imagined Congress passing a taxation law and, under the necessary and proper clause:[184]

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states by summary proceedings, such as distress and sale, which did not provide for jury trial; (3) it was undesirable to have juries sit in tax collection cases because a "dilatory" jury trial "would neither suit the exigencies of the public, nor promote the convenience of the citizens . . ."; and (4) improper conduct of revenue officers was taken care of by the provision of a jury in criminal cases. *Id.* Hamilton seriously undercut these points, however, by arguing a few pages later (*id.* at 568) that juries should not be permitted to sit in prize cases involving relations with foreign nations because of the danger of jury disregard of the law and "[t]hough the proper province of juries to be to determine matters of fact, yet in most cases legal consequences are complicated with fact in such a manner as to render a separation impracticable." The latter, no doubt, was precisely the point of those who wished to have juries sit in taxation cases.

The federalists realized full well that one consequence of having a jury decide a case is that the result might be against the declared law that should govern the case. *See, e.g.*, the federalist Hugh Henry Brackenridge in The Pittsburgh Gazette, April 1788, in P. Ford, Essays On The Constitution 320 (1892); James Wilson in the Pennsylvania ratification convention, 2 Elliot, Debates, *supra* note 44, at 516-17.

184. 3 Elliot, Debates, *supra* note 44, at 218.

> suppose they should be of opinion that the right of the trial by jury was not one of the requisites to carry it into effect; there is no check in this Constitution to prevent the formal abolition of it.... Our great unalienable rights ought to be secured from being destroyed by such unlimited powers, either by a bill of rights, or by an express provision in the body of the Constitution.

The most that can fairly be argued from this alone is that Monroe might have been expressing a more than hypothetical concern that Congress actually might attempt to conjoin a tax measure with a provision setting aside trial by jury in tax cases.

At a later point in the Virginia debates, and during consideration of article III, Patrick Henry noted that the federal judiciary very likely would have jurisdiction over disputes arising out of the collection of federal taxes. He expressed the fear that the federal courts would sit several hundred miles form the place where federal tax collectors were operating, perhaps illegally. Henry then noted that Congress might or might not provide for trial by jury in civil cases.[185] Perhaps the conjoined references to difficulties in the enforcement of federal taxation laws and trial by jury in civil cases was intended to suggest to the mind of the listener the same idea of salvation through jury law-making that seems also to have been implied by the repeated simultaneous references to debtors and the civil jury. There were similar joint references to the civil jury trial problem and

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185. *Id.* at 577-78. *Cf.* Patrick Henry in the Virginia ratification convention, *id.* at 503, 512-13.

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Congress' broad powers in the speeches and writings of other antifederalists.[186]

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186. *See* George Mason in the Virginia ratification convention, 3 ELLIOT, DEBATES, *supra* note 44, at 441-42. *See also* Robert Whitehill in the Pennsylvania ratification convention, MCMASTER & STONE, *supra* note 85, at 780 (treaty power). Writing as "A Farmer" in the *Philadelphia Independent Gazetteer*, April 22, 1788 (MCMASTER & STONE, *supra* note 85, at 539), an anonymous antifederalist joined his objections to the extensive spending and taxing powers of Congress and the absence of a guarantee of civil jury trial:

> The Congress, by the proposed system, have the power of borrowing money to what amount they may judge proper, consequently to mortgage all our estates, and all our sources of revenue. The exclusive power of emitting bills of credit is also reserved to Congress. They have, moreover, the power of instituting courts of justice without trial by jury, except in criminal cases, and under such regulations as Congress may think proper to decide, not only in such cases as arise out of all the foregoing powers, but in the other cases which are enumerated in the system.

The antifederalist John Smilie objected in the Pennsylvania ratification convention to the absence of a guarantee of civil jury trial. Among other problems. Smilie worried that "[t]here may be Danger in the Execution of the judicial Department as in the Case of a rigorous Collection of direct Taxes. — A Quarrel between a Collector and a Citizen would drag the Citizen into the Court of Congress." MCMASTER & STONE, *supra* note 85, at 780.

In his pamphlet *The Genuine Information* (1788), the then antifederalist Luther Martin of Maryland also discussed the question of the enforcement of the federal tax laws and the federal courts in the context of the taxpayer being

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Another important function of the civil jury, according to the antifederalists, was to provide the common citizen with a sympathetic forum in suits against the government. "A Democratic Federalist" writing in the *Pennsylvania Packet* on October 23, 1787, reminded readers of a recent outrageous search by a constable who was subsequently mulcted in damages by a jury in a civil action. The writer stated that it was quite predictable that a "lordly court of justice" sitting without a jury in the federal court would likely be "ready to protect the officers of government against the weak and helpless citizens. . . . What

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required to go to undue expense — because of the necessity, alleged by the antifederalists, of being required to re-try factual questions before the Supreme Court — in order ultimately to prevail against a tax collector. Martin did not, however, mention jury trial in this context. *See* 1 ELLIOT, DEBATES, *supra* note 44, at 382. The antifederalists had argued during the Maryland ratification convention (in which Martin served as delegate and presumably was a leading figure) in favor of an amendment to the Constitution that would have made it clear that appeals in revenue cases were to reach "as well to matter of fact as law." 2 *id.* at 550; *see* note 168 *supra* and accompanying text. This provision must be viewed, however, in the light of its accompanying amendment which would have limited federal court jurisdiction in all cases, revenue cases included, to those in which the amount in controversy exceeded a sum to be set in the amendment. Probably the antifederalists intended this figure to be high enough so that the litigant, for example in a revenue case, would not be unduly inconvenienced by the greater expense of litigating in federal courts. See also the altercation in the Pennsylvania ratification convention over the issue of civil jury trial in Sweden (MCMASTER & STONE, *supra* note 85, at 359-65); and the argument of George Mason in the Virginia ratification convention with respect to the danger of control by Congress over the decisions of juries in civil cases in the court at the seat of government. 3 ELLIOT, DEBATES 431; *see* note 111 *supra*.

refuge shall we then have to shelter us from the iron hand of arbitrary power?"[187]

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187. McMaster & Stone, *supra* note 85, at 154. The account given by the antifederalist author is interesting:

> Suppose, therefore, that the military officers of Congress, by a wanton abuse of power, imprison the free citizens of the United States of America; suppose the excise or revenue officers (as stable, having a warrant to search for stolen goods, pulled down the clothes of a bed in which there was a woman and searched under her shift — suppose, I say, that they commit similar or greater indignities, in such cases a trial by jury would be our safest resource [sic], heavy damages would at once punish the offender and deter others from committing the same . . . .

I have not been able to locate the case to which the author refers.

One of the lowest blows in the vigorous newspaper and pamphlet war that was waged over the question of the ratification of the Constitution was aimed by Eldridge Gerry, the Massachusetts antifederalist who had refused to sign the Constitution. Writing as "a Columbian Patriot" in his otherwise anonymous pamphlet *Observations on the New Constitution, and on the Federal and State Conventions*, Gerry asked:

> [S]hall this inestimable privilege be relinquished in America — either thro' the fear of inquisition for unaccounted thousands of public monies in the hands of some who have been officious in the fabrication of the *consolidated system*, or from the apprehension that some future delinquent possessed of more power than integrity, may be called to a trial by his peers in the hour of investigation.

P. Ford, Pamphlets On The Constitution 9-10 (1888). In addition to the obvious scurrilities intended, it would also appear that Gerry is implying that federal judges might in some case not be sufficiently firm to *enforce* the law as it should be.